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VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/126,816	07/31/98	VON EICHEL-STREIBER	PM254992

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EXAMINER

BURKE, J

ART UNIT

1642

PAPER NUMBER

7

DATE MAILED: 09/24/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/126,816

Applicant(s)

Von Eichel-Streiber et al

Examiner  
Julie E. Burke, (Reeves), Ph.D.

Group Art Unit  
1642



☐ Responsive to communication(s) filed on \_\_\_\_\_.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire zero month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-11 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-11 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been  
☒ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1642

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-2, in part and claims 3-6, drawn to a method of treating a patient by administering an immunotoxin, classified in class 424, subclass 181.1. If group I is elected, than claims 1-2 will be examined to the extent that they read upon an immunotoxin comprising an antibody variable domain.
  - II. Claims 1-2, in part, drawn to a method of treating a patient by administering a composition comprising a targeting agent coupled to a toxin, classified in class 514, subclass 12, for example, if the targeting agent is a protein, ro example. If group II is elected, claims 1-2 will be examined to the extent that they do not read upon an immunotoxin comprising an antibody variable domain, but that they read upon other toxin-targeting compounds such as a ligand which binds to a specific receptor.
  - III. Claims 7-9 and 10, drawn to an immunotoxin or a composition comprising an immunotoxin and method of manufacturing such, classified in class 530, subclass 391.7.
  - IV. Claim 11, drawn to a method of contacting cells with a retroviral for transformation of tumor cells, classified in class 536, subclass 23.4.
2. The inventions are distinct, each from the other because of the following reasons:
3. The methods of Inventions I, II and IV differ in the method objectives, method steps and parameters and in the reagents used. Invention I recites to a method of treating a patient by

Art Unit: 1642

administering an immunotoxin, Invention II recites method of treating a patient by administering a composition comprising a targeting agent coupled to a toxin, and Invention IV recites a method of contacting cells with a retroviral for transformation of tumor cells. The compounds used in the practice of invention I, II and IV are materially different. The examination of all groups would require different searches in the U.S. PATENT SHOES and the scientific literature and would require the consideration of different patentability issues. Thus Inventions I, II and IV are separate and distinct in having different method steps and different endpoints and are patentably distinct.

4. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of administering a ligand-toxin, for example, as encompassed in group II demonstrates that the process can be practiced with a materially different product than the immunotoxin. Thus the inventions are patentably distinct..

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. A telephone call was made to Ann Hobbs on 22 Sept 1999 to request an oral election to the above restriction requirement, but did not result in an election being made.

Art Unit: 1642

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie E. Burke, nee Reeves, Ph.D. whose telephone number is (703) 308-7553.



Julie E. Burke, nee Reeves, Ph.D.

September 22, 1999

JULIE BURKE  
PRIMARY EXAMINER